DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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91125d

April 4, 2001

WARNING LETTER

NWE-16-01W

VIA FEDERAL EXPRESS

Theodora Lelecas, President
Holles Laboratories, Inc.
30 Forest Notch
Cohasset, Massachusetts 02025

Dear Ms. Lelecas:

During an inspection of your establishment located in Cohasset, Massachusetts, on March 8 and 9, 2001, our Investigator determined that your establishment manufactures Fluoresoft-0.35%. Fluoresoft-0.35% is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1) Failure to validate and approve by an established procedure a process where its results cannot be fully verified by subsequent inspection and test. For example, the aseptic filling operation has not been validated to assure sterility of the Fluoresoft-0.35%.

2) Failure to establish and maintain procedures for implementing corrective and preventative actions (CAPA). For example, you have no written corrective and preventative action (CAPA) procedures.

3) Failure of your device master record (DMR) to provide the following:

a) an acceptable specification for the Fluorescence test, performed with the Fluorometer on each batch. Further your response to the FDA-483 that we received on March 27, 2001, had a specification of [redacted] The worksheets the Investigator collected had many results that fell above and below your specifications.

b) there are no labeling specifications for the labeling on the Fluoresoft ampuls, foil packets, boxes or package inserts.

4) Failure to establish written procedures for finished device acceptance. For example, no written procedures for the determination of sodium, potassium, chloride and phosphate.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your Quality System.

We acknowledge receipt of your response to the FDA-483 on March 27, 2001 and found it unacceptable for the reasons listed in the Warning Letter.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violation related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviation may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will no recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Bruce, R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,

Gail T. Costello for
District Director
New England District Office